

CHARGE: 502 (a)—the labeling accompanying the article while held for sale contained false and misleading representations that the article was an adequate and effective treatment for gallstones and for cleansing the liver; and 502 (f) (2)—the article was essentially a laxative, and its labeling, while held for sale, failed to warn against use of the article when symptoms of appendicitis are present and failed also to warn that frequent or continued use of the article may result in dependence on laxatives.

DISPOSITION: 1-26-55. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

4751. Posterior pituitary injection. (F. D. C. No. 37287. S. No. 88-418 L.)

QUANTITY: 44 cartoned vials at Buffalo, N. Y., in possession of Direct Laboratories, Inc.

SHIPPED: 2-24-53, from Chicago, Ill.

LABEL IN PART: (Carton & vial) "No. 2261 10 cc. vial Posterior Pituitary Injection (Surgical) Double U. S. P. strength Each 1 cc. represents: Posterior Pituitary 20 USP units Chlorobutanol 5 mg. (8/100 gr.) * * * Water for injection USP q. s. 1 cc. * * * Administration: Intramuscular or Subcutaneous. * * * Direct Laboratories, Inc. Buffalo 4, New York."

RESULTS OF INVESTIGATION: The article was shipped in bulk, and after its receipt by the consignee, it was repackaged and relabeled. Examination showed that the article contained 73 percent of the declared posterior pituitary potency instead of 85 percent as required by the United States Pharmacopeia.

LIBELED: 10-4-54, W. Dist. N. Y.

CHARGE: 501 (b)—the strength of the article while held for sale differed from the standard for posterior pituitary injection set forth in the United States Pharmacopeia.

DISPOSITION: 11-4-54. Default—destruction.

4752. Chorionic gonadotropin. (F. D. C. No. 37649. S. No. 77-276 L.)

QUANTITY: 99 packages at Philadelphia, Pa.

SHIPPED: 8-16-54, from Los Angeles, Calif.

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than 50 percent of the declared amount of chorionic gonadotropin potency.

LIBELED: 2-9-55, E. Dist. Pa.

CHARGE: 501 (c)—the strength of the article while held for sale differed from that which it was represented to possess; and 502 (a)—the label statement "Chorionic Gonadotropin (Lyophilized) 5,000 I. U." was false and misleading.

DISPOSITION: 4-4-55. Default—destruction.

4753. Liver-folic acid B₁₂. (F. D. C. No. 37509. S. No. 89-577 L.)

QUANTITY: 63 vials at Minneapolis, Minn.

SHIPPED: 9-3-54, from Philadelphia, Pa.

RESULTS OF INVESTIGATION: Analysis showed the article contained approximately 70 percent of the declared amount of vitamin B₁₂.

LIBELED: 12-9-54, Dist. Minn.

*See also No. 4745.